

**APPARATUS AND METHOD FOR ADMINISTRATION OF MEDICATION**

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**Abstract of WO0105352**

Apparatus and method for the mucosal administration of medication. The apparatus has a vehicle adapted for delivery of said medication. The vehicle is retrievable after use to allow a supervisor to ensure that the medication has been correctly administered and to prevent misuse of any unadministered drug. Typically the vehicle is adapted to be retrievable substantially intact after delivery.

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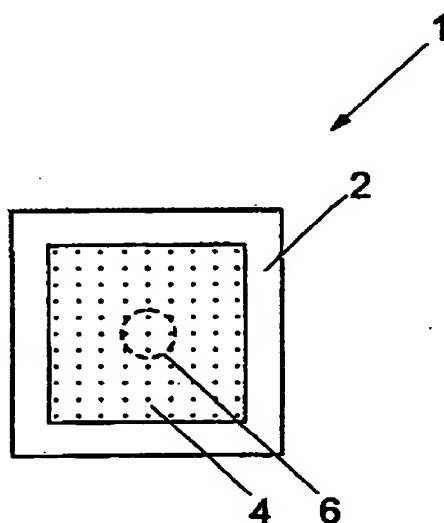
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## (54) Title: APPARATUS AND METHOD FOR ADMINISTRATION OF MEDICATION



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(57) Abstract: Apparatus and method for the mucosal administration of medication. The apparatus has a vehicle adapted for delivery of said medication. The vehicle is retrievable after use to allow a supervisor to ensure that the medication has been correctly administered and to prevent misuse of any unadministered drug. Typically the vehicle is adapted to be retrievable substantially intact after delivery.

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10 **Apparatus and Method for Administration of Medication**

11

12 This invention relates to an apparatus and method for  
13 administration of medication.

14

15 Opiate/opioid addicts may be treated by controlled  
16 administration of substitute medication. Some such  
17 substitute medication is normally administered by  
18 mucosal route under supervision. However such  
19 medication has more potent effect if injected or  
20 "snorted". There is also a thriving black market for  
21 such medication. It is relatively simple for a patient  
22 to divert such medication for alternative use or  
23 resale, even when it is administered under supervision.

24

25 According to the present invention there is provided an  
26 apparatus for the mucosal administration of medication  
27 comprising a vehicle adapted for delivery of said  
28 medication.

29

30 Said vehicle may be retrievable after use. Typically  
31 said vehicle is adapted to be retrievable substantially  
32 intact after delivery.

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2 Preferably said vehicle is adapted to enclose said  
3 medication. Additionally or alternatively said vehicle  
4 may be adapted to be impregnated with said medication.

5

6 Said vehicle may be adapted to fit in the mouth. Said  
7 vehicle may be adapted to fit under the tongue.

8

9 Preferably said vehicle is comprised of material inert  
10 to saliva. More preferably said vehicle is comprised  
11 of material permeable to saliva.

12

13 Typically said vehicle comprises a permeable container.

14

15 Preferably said container is adapted to receive  
16 medication during its manufacture.

17

18 Said container is preferably adapted to accommodate  
19 medication in solid form. Said solid form may comprise  
20 a tablet. Said solid form may comprise a frozen  
21 liquid.

22

23 Preferably said container is sealed. Alternatively  
24 said container is adapted to be sealed.

25

26 Further according to the present invention there is  
27 provided a method of administration of medication  
28 comprising the steps of:  
29 including said medication in a vehicle;  
30 supervising a patient while the vehicle is placed in a  
31 patient's mouth;

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1 waiting until the contents of the vehicle have been  
2 absorbed into the patient's bloodstream;  
3 reclaiming the vehicle; and  
4 ensuring the vehicle is intact.

5

6 Preferably said method comprises the step of sealing  
7 said medication within a permeable container. More  
8 preferably said method comprises the step of sealing  
9 said medication within a permeable container during  
10 manufacture of said container.

11

12 Embodiments of the present invention will now be  
13 described by way of example only with reference to the  
14 accompanying drawings in which:

15

16 Fig 1 is a permeable container in accordance with an  
17 aspect of the invention; and

18

19 Fig 2 is a permeable container in accordance with a  
20 further aspect of the invention.

21

22 Referring to the drawings, an apparatus for the mucosal  
23 administration of medicament comprises a vehicle 1 in  
24 the form of a container 2, 3 substantially of permeable  
25 material. The container 2, 3 is manufactured of  
26 material that is permeable to saliva, and that does not  
27 react with saliva.

28

29 In the embodiment illustrated in Fig 1, the container 2  
30 comprises a sealed pouch 4 of permeable material.  
31 Medication 6 is placed within the pouch 4 during  
32 manufacture of this container 2, and the pouch 4 is

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1       then sealed. The medication is thus contained within  
2       the sealed pouch.

3

4       In the embodiment illustrated in Fig 2, the container 3  
5       comprises a pouch 8 with an opening 10, wherein the  
6       opening 10 is adapted to be sealed. The opening 10  
7       permits inclusion of a medicament. In this embodiment  
8       the pouch 8 is substantially of material that contains  
9       a percentage of nylon. The edges of the opening 10 of  
10      the pouch can be fused by heat sealing once a  
11      medicament is placed therein.

12

13      Each vehicle 1 comprises a unique identifier to prevent  
14      its substitution.

15

16      This vehicle 1 is useful in administration of  
17      opiate/opiod medication to patients.

18

19      An example of appropriate patients would be recovering  
20      drug addicts. There is always the temptation for such  
21      patients to attempt to divert the medication for later  
22      more potent use or resale. For this reason, the  
23      medication is administered under supervision.

24

25      The medication is normally in tablet form and adapted  
26      to be delivered by mucosal route. That is, the  
27      medicament is designed to be absorbed under the tongue  
28      or elsewhere within the mouth. Tablets used for this  
29      purpose are small and easily hidden.

30

31      The administrator presents tablets to the patient in  
32      the sealed container 2,3 of the invention, which he

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1 then retrieves - still sealed - when empty. This  
2 allows the administrator to be satisfied that the  
3 contents of the container 2,3 have been absorbed into  
4 the bloodstream of the patient, and not diverted for  
5 other purposes.

6

7 That is, since the vehicle 1 is recoverable intact,  
8 there is a great degree of confidence that the  
9 medication has been properly administered to the  
10 intended patient.

11

12 The vehicle 1 of the instant invention also allows  
13 administrators of medication to reduce the possibility  
14 of diversion of medication with black market resale  
15 value if it becomes a requirement that a repeat  
16 prescription is only available on return of intact  
17 containers 2,3. This will reduce the likelihood of  
18 diversion of such medication for sale, for example by  
19 pensioners.

20

21 In a further embodiment the structure of the vehicle 1  
22 is impregnated with the medicament; or impregnated with  
23 or made from material that reacts with medication  
24 accommodated in the container 2,3 on dispensing.

25

26 The vehicle 1 also has application in administration of  
27 drugs to unconscious or disabled patients. The size,  
28 shape or nature of the vehicle 1 is adapted to prevent  
29 inadvertent inhalation or swallowing of the vehicle 1.

30

31 For this purpose, the vehicle 1 has a portion adapted  
32 to protrude from the mouth when it is in position. The

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1 protruding portion operates as a handle, allowing an  
2 administrator to retain control of the vehicle 1, and  
3 allowing easy removal of the spent vehicle 1 from a  
4 patient's mouth. In one embodiment, the protruding  
5 portion is a string or cord.

6

7 Details concerning the contents of the vehicle 1, for  
8 example the dosage or patient's name or a serial number  
9 or date, can be printed and displayed or otherwise  
10 included on the surface of the material that comprises  
11 the vehicle 1.

12

13 The vehicle 1 can be impregnated with, or otherwise  
14 contain a pH indicator. That is, the vehicle 1 can be  
15 customised for specific purposes.

16

17 The container 2, 3 will accommodate medication in  
18 tablet form, or in any solid form such as a frozen  
19 liquid.

20

21 In the embodiments of Figure 1 and Figure 2, the  
22 container 2,3 is soft and porous, and resembles a  
23 teabag. The material from which teabags are  
24 manufactured is ideal for this vehicle 1. In use,  
25 medication 6 in tablet form is enclosed within this  
26 container 2,3. The medication 6 is either sealed in  
27 the container 2 during its manufacture, or the  
28 container 3 is filled and sealed by or on behalf of the  
29 administrator. Each vehicle 1 contains a unique  
30 identifier, such as a serial number.

31 The sealed container 2,3 is dispensed to the patient.  
32 The patient is observed while he places the container

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1       2,3 in his mouth or under his tongue, for the period  
2       during which the medication is dissolving and being  
3       absorbed, and as he removes the empty container 2,3  
4       from his mouth.

5

6       The administrator can then use the unique identifier to  
7       satisfy himself that there has been no replacement of  
8       containers 2,3 during this process. If this is the  
9       case, the administrator can then examine the container  
10      2,3 to satisfy himself that the container 2,3 has not  
11      been tampered with, and remains intact.

12

13      The container 2,3 can also be made of material that is  
14      designed to dissolve, but at a rate slower than that of  
15      the medication it is adapted to contain. The surface  
16      of the vehicle 1 can be impregnated with medication.

17

18      In one embodiment, the vehicle 1 comprises a piece of  
19      material impregnated with a medicament. This  
20      embodiment of the vehicle 1 does not require to be  
21      sealed, but is still retrievable intact by the  
22      administrator.

23

24      A further embodiment of the vehicle 1 comprises a  
25      container 2,3 the surface of which can be impregnated  
26      with material that changes the properties of the  
27      medication contained in the container 2,3 on  
28      dispensing.

29

30      The vehicle 1 can be used to administer medication to  
31      unconscious patients, and to monitor its absorption.

32

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1       The vehicle 1 has application in administering  
2       medication to patients who require supervision to  
3       ensure that the medication is taken, such as geriatric  
4       and paediatric patients. The vehicle 1 can be  
5       coloured, flavoured, patterned or otherwise decorated  
6       to make more palatable to children.

7

8       The vehicle 1 has further application for veterinary  
9       use.

10

11      The common features of all embodiments of the vehicle 1  
12      are that they remain intact throughout the procedure of  
13      administration of medication, and are retrievable for  
14      scrutiny after administration to confirm that  
15      medication has been appropriately administered.

16

17      Improvements and modifications can be made to the above  
18      without departing from the scope of the invention.

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**1            CLAIMS**

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2 9. Apparatus as claimed in any preceding claim,  
3 wherein said vehicle is comprised of material  
4 permeable to saliva.

5

6 10. Apparatus as claimed in any preceding claim,  
7 wherein said vehicle comprises a permeable  
8 container.

9

10 11. Apparatus as claimed in Claim 10, wherein said  
11 container is sealed.

12

13 12. Apparatus as claimed in Claim 10, wherein said  
14 container is adapted to be sealed.

15

16 13. Apparatus as claimed in any preceding claim,  
17 wherein said container is adapted to receive  
18 medication during its manufacture.

19

20 14. Apparatus as claimed in any preceding claim,  
21 wherein said container is adapted to accommodate  
22 medication in solid form.

23

24 15. Apparatus as claimed in Claim 14, wherein said  
25 solid form comprises a tablet or said solid form  
26 comprises a frozen liquid.

27

28 16. Method for administration of medication comprising  
29 the steps of:  
30 including said medication in a vehicle;  
31 supervising a patient while the vehicle is placed  
32 in a patient's mouth;

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1        waiting until the contents of the vehicle have  
2        been absorbed into the patient's bloodstream;  
3        reclaiming the vehicle; and  
4        ensuring the vehicle is intact.

5

6        17. Method as claimed in claim 16, wherein the method  
7        further comprises the step of sealing said  
8        medication within a permeable container.

9

10      18. Method as claimed in either of claims 16 or 17,  
11      wherein the method further comprises the step of  
12      sealing said medication within a permeable  
13      container during manufacture of said container.

14

15      19. Apparatus for mucosal administration of medication  
16      substantially as hereinbefore described with  
17      reference to the accompanying drawings.

18

19      20. Method for administration of medication  
20      substantially as hereinbefore described with  
21      reference to the accompanying drawings.

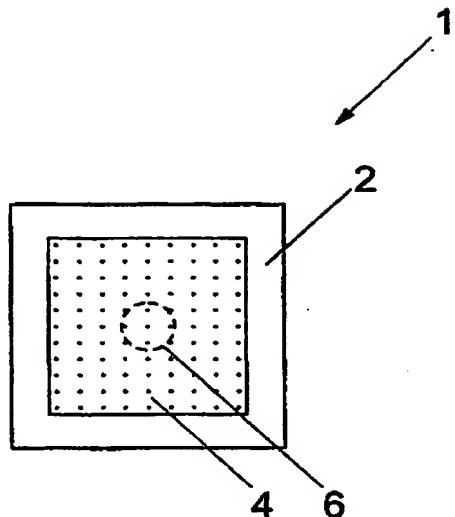
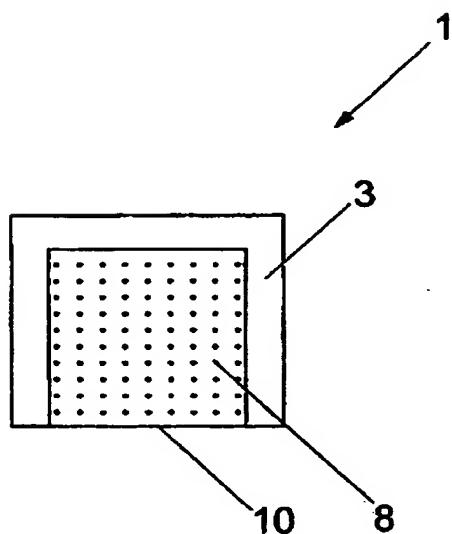
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*Fig. 1**Fig. 2***SUBSTITUTE SHEET (RULE 26)**

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 00/02758

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61J7/00 A61J1/03 A61K9/70

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61J A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 167 244 A (KJERSTAD RANDY E) 1 December 1992 (1992-12-01) column 5, line 14 - line 26 column 5, line 50 - line 57; figures	1-14, 17-20
X	WO 91 03271 A (UNIV UTAH RES FOUND) 21 March 1991 (1991-03-21) page 22, line 3 - line 11; figures 1-16	1-10, 14, 15, 19, 20
X	US 3 948 254 A (ZAFFARONI ALEJANDRO) 6 April 1976 (1976-04-06) column 4, line 41 - line 47 column 20, line 24 - line 38; figures 1-5	1-10, 14

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

## \* Special categories of cited documents :

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Date of the actual completion of the International search

10 November 2000

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## INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l. Appl. No.  
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